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June 16, 2008 09:48 AM Eastern Daylight Time **US WorldMeds Completes Phase III Trial of Lofexidine for Treatment of Opiate Withdrawal Symptoms*****Initial results show that opiate-dependent patients taking Lofexidine experience a significant reduction in withdrawal symptoms and stay in detoxification treatment longer***

LOUISVILLE, Ky.--([BUSINESS WIRE](#))--US WorldMeds, a Kentucky-based specialty pharmaceutical company, today announced that a recently completed Phase III clinical trial investigating the use of lofexidine hydrochloride (Lofexidine) for the treatment of opiate withdrawal symptoms in patients undergoing opiate detoxification has shown that opiate-dependent patients taking the drug experienced a significant reduction in withdrawal symptoms at the anticipated peak of withdrawal and stayed longer in detoxification treatment as compared to patients taking placebo.

"The debilitating withdrawal symptoms associated with opiate detoxification are a major reason people struggling with heroin or prescription drug addiction avoid or leave treatment," said Paul Breckinridge "Breck" Jones, CEO of US WorldMeds. "These trial results are impressive and confirm our expectations for Lofexidine. Lofexidine promises to be an important new tool for treating opiate addiction here in the US."

Lofexidine is being developed as a non-addictive, non-narcotic treatment for relieving withdrawal symptoms associated with opiate detoxification. Opiates include the illicit drug heroin and prescription drugs such as oxycodone (e.g. OxyContin[®]) and hydrocodone (e.g. Vicodin[®]). Typical opiate withdrawal symptoms include vomiting, sweating, stomach cramps, diarrhea, and muscle pain.

If approved by the US Food and Drug Administration (FDA), Lofexidine would be the first non-addictive, non-narcotic treatment approved in the United States for relieving withdrawal symptoms associated with opiate detoxification. Currently, the only FDA-approved treatment options for opiate detoxification are medications such as methadone and buprenorphine, which are opiate derivatives and have addictive properties.

US WorldMeds initiated the randomized, double-blind Phase III clinical trial for Lofexidine in June 2006 as a collaborative effort between the company, the National Institute on Drug Abuse (NIDA) and the Department of Veterans Affairs (VA) Cooperative Studies Program Coordinating Center in Perry Point, MD. The trial was designed to evaluate the effectiveness of Lofexidine in reducing withdrawal symptoms in subjects undergoing opioid detoxification. Additionally, the trial sought to assess whether Lofexidine increased the number of patients who completed detoxification treatment, whether the drug was safe, and other secondary objectives.

The Phase III trial for Lofexidine involved 264 adult patients – 200 male and 64 female – who had a proven dependence on an opioid such as heroin, morphine, or oxycodone. Study subjects were admitted to one of 15 clinical trial sites throughout the United States for this eight-day, inpatient study. As a primary measure of effectiveness, the severity of the subjects' withdrawal symptoms was evaluated using the Short Opiate Withdrawal Scale (SOWS-Gossop), a subjective assessment in which patients rate their individual withdrawal experiences. Study subjects were free to withdraw from the study at any time.

The statistical analysis of the primary efficacy endpoints of the Phase III trial is now complete. The initial results demonstrate Lofexidine's statistical significance versus placebo in reducing withdrawal symptoms associated with opiate detoxification on the third day of treatment, which is the expected peak point for withdrawal symptoms. Also, patients taking Lofexidine in the trial stayed in detoxification treatment longer than patients taking placebo.

"This trial has shown that Lofexidine can both reduce peak withdrawal symptoms associated with opiate detoxification and help people remain in an opiate detoxification program such as the one studied," said Dr. Charles Gorodetzky, Medical Director of US WorldMeds. "These benefits, combined with the fact that Lofexidine would be the first non-addictive, non-narcotic medication of its kind on the US market, make it a potentially important new tool in managing patients during the critical opiate withdrawal period."

NIDA estimates that drug and alcohol addiction costs the United States greater than \$500 billion each year in lost earnings, healthcare expenditures, and costs associated with accidents and crime. Opioid addiction, which includes the use of illegal drugs such as heroin and the non-medical use of medications such as methadone, morphine, oxycodone (e.g. OxyContin[®]) and hydrocodone (e.g. Vicodin[®]), impacts millions of American families annually. In the September 2007 National Survey on Drug Use and Health, the US Substance Abuse and Mental Health Services Administration (SAMHSA) reported that nearly 3.8 million Americans have used heroin in their lifetimes and that approximately 560,000 used the drug in 2006. The survey also showed that more than 4 million Americans have illicitly used OxyContin[®] in their lifetimes and that 1.3 million illicitly used the prescription medication in 2006.

Lofexidine, an alpha-2-adrenergic agonist, has been studied in six prior clinical trials in the United States. Lofexidine therapy is associated with common side effects including hypotension, bradycardia, dry mouth, and sedation.

Lofexidine has been approved for use for 15 years in the United Kingdom (UK) to manage the often debilitating withdrawal symptoms that occur during opiate detoxification. It is marketed in the UK by Britannia Pharmaceuticals as BritLofex[®]. US WorldMeds acquired a license for Lofexidine from Britannia in 2003.

Given the encouraging initial results of the Phase III clinical trial, US WorldMeds intends to submit a new drug application (NDA) for Lofexidine with the FDA for US approval. The NDA will be filed after the complete dataset from the trial, including additional



efficacy and safety measures, is analyzed, and additional required studies are completed.

The following medical facilities were involved in the Phase III Lofexidine trial:

- Alexian Brother Behavioral Health Hospital, Hoffman Estates, IL
- Atlanta Center for Medical Research, Atlanta, GA
- Aurora Psychiatric Hospital, Wauwatosa, WI
- CNS Psychiatric Institute of Washington, Washington, D.C.
- Lake Charles Clinical Trials, LLC, Lake Charles, LA
- North Miami Research, Inc, North Miami, FL
- Providence VA Medical Center/ Ocean State Research Institute, Providence, RI
- Research Across America, Dallas, TX
- St. Vincent Catholic Medical Center & Richmond University Medical Center, Staten Island, NY
- University of Kentucky Center for Human Behavioral Science, Lexington, KY
- University of Texas Health Science Center, San Antonio, TX
- Vanderbilt Psychiatric Hospital, Nashville, TN
- VA Puget Sound Health Care System/ The Seattle Institute for Biomedical and Clinical Research, Seattle, WA
- VA Salt Lake City Healthcare System/ Western Institute of Biomedical Research, Salt Lake City, UT
- Wayne State Addiction Research Institute, Detroit, MI

About US WorldMeds

US WorldMeds is a closely held specialty pharmaceutical company based in Louisville, Kentucky. Founded in 2001, US WorldMeds is focused on identifying, developing and commercializing therapeutic treatments for niche patient populations. For more information, please visit <http://www.usworldmeds.com>.

Contacts

For US WorldMeds
Nicole Cottrill, 615-327-7999
Mobile: 615-397-7823